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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,745

12/07/2005

Takayoshi Mamine

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,745	<b>Applicant(s)</b> MAMINE ET AL.	
	<b>Examiner</b> MELANIE YU	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of group II, claims 4-7, in the reply filed on 26 March 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-3 and 8 are withdrawn as being drawn to a non-elected invention.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the Continuing Data is currently placed at the end of the "Technical Field" statement and should be mentioned in the first paragraph of the specification under its own heading.

Appropriate correction is required.

### ***35 USC § 112, sixth paragraph***

3. In claim 1, line 4, The 3-prong analysis for determining if 35 U.S.C. 112 6th paragraph is being invoked (MPEP 2181). The phrase "substrate holding means adapted for" does not invoke 35 U.S.C. 112, sixth paragraph. The term "adapted" does not conform to the specific phrase "means for" which required by the first prong of the test.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner et al. (US 2002/0168652).

Werner et al. teach an assaying apparatus comprising: a substrate holding means adapted for holding and rotationally driving a substrate for bioassay (biodisc drive assembly, biodisc is the substrate and drive assembly holds and rotates the biodisc, par. 7 and 91), the substrate including a reaction region adapted so that the sample material and fluorescence marking agent are permitted to be dropped from the upper side (inlet port, 132, is on upper side of substrate, 110, Fig. 22A-D; and 132, Fig. 26; sample and reporters are injected through inlet port which is on the upper side of the substrate, par. 88), and the probe material is permitted to be immobilized (capture DNA are immobilized probes, par. 88), the reaction region serving as a field of mutual reaction between the probe material and the sample material (target DNA hybridizes with capture DNA, par. 88) and being such that plural wells to which fluorescence, with respect to the fluorescence marking agent, is irradiated from the lower side are formed (wells are fluidic channels and a plurality of fluidic channels are present on a single substrate which is in the form of a disc, par. 67) and an information region where light is irradiated from the lower side to thereby have ability to record and/or reproduce information (assay results are recorded as information on the underside of the biodisc, biodisc also has encoded information about the assay which is reproduced in the form of rotation rate and processing information, par. 7 and 91; biodisc is interrogated by read beam of the drive assembly, which is a light that irradiates the lower side, par. 7

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and 91); a fluorescence detection optical system for irradiating fluorescence (hardware and optics are present for fluorescence detection, par. 48) having a predetermined wavelength with respect to the reaction region of the bioassay substrate to detect presence or absence of the fluorescence having the predetermined wavelength produced from the fluorescence marking agent in accordance with the fluorescence (bead binding and therefore presence and absence of fluorescence is determined by detection of fluorescence using a fluorometer, par. 48, 49 and 62; fluorescent beads are excited and fluoresce at specific wavelengths, par. 140 and Table 4); and an information recording/reproducing optical system for irradiating light having a predetermined wavelength with respect to the information of the bioassay substrate to perform recording and/or reproducing operations of information on the basis of a reflected light thereof (read beam of the drive reads and records information from the biodisc and therefore has a predetermined wavelength, par. 7; reflective area of biodisc encoded with information interacts with the reflected beam and sends data to the processor, par. 91).

Regarding claim 5, Werner et al. teach the bioassay substrate formed so the entirety is a circular-plate shape (substrate is a disc, 110, Fig. 1; par. 120) and the substrate holding means rotationally drives with the circular plate center being the center (rotated around the circle in the center of the disc, Fig. 27).

With respect to claim 6, Werner et al. teach the bioassay substrate comprised of a substrate including an upper layer portion (upper layer of substrate, 146, has immobilized probes which is the upper layer portion, 158, Fig. 8 and 10) and a lower

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layer portion formed at the lower side thereof (reflective information on lower layer of the biodisc, par. 91; 146, Fig. 5) and includes the reaction region at the upper layer portion (upper layer of substrate, 146, has immobilized probes which is the upper layer portion, 158, Fig. 8 and 10; par. 106) and the information region at the lower layer portion (reflective information on lower layer of the biodisc, par. 91; 146, Fig. 5).

Regarding claim 7, Werner et al. teach the information region formed at a position spaced from depth of focus of the fluorescence and light for information recording in a thickness direction of the substrate from the reaction region (information region is bottom of the substrate and the reaction region is on the top of the substrate, therefore the two regions are spaced apart by the substrate thickness, par. 67 and 102).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Patent Examiner, Art Unit 1641